

OCT 18 1999  
PATENT & TRADEMARK OFFICE 0505  
**SUPPLEMENTARY**  
**LIST OF ART CITED BY APPLICANT**

ATTY. DOCKET: 17310(AP)	SERIAL NO.: 09/371,354
APPLICANT: Stephen Donovan	TITLE: Method For Treating Cardiac Muscle Disorders
FILING DATE: August 10, 1999	GROUP: <del>3734</del> 1647

**U.S. PATENT DOCUMENTS**

*EXAMINER INITIAL		DOCUMENT NO.	DATE	NAME	CLASS	SUB-CLASS	FILING DATE (if applicable)
	AA						
	AB						

**FOREIGN PATENT DOCUMENTS**

		DOCUMENT NO.	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION (yes/no)
	BA						
	BB						

**OTHER ART**

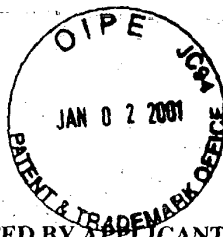
(Including Author, Title, Date, Pertinent Pages, etc.)

<i>EEB</i>	CA	Ayers, G.M., et al.; <i>Amiodarone Instilled Into the Canine Pericardial Sac Migrates Transmurally to Produce Electrophysiologic Effects and Suppress Atrial Fibrillation</i> ; <u>Journal of Cardiovascular Electrophysiology</u> ; Vol. 7, No. 8; August 1996; 713-721.
	CB	Lamanna, C., et al.; <i>Cardiac Effects of Botulinal Toxin</i> ; <u>Arc. Int. Pharmacodyn.</u> ; 1988; Vol. 293; 69-83.
	CC	Lamanna, C.; <i>Thoughts on Action of Botulinum Toxin Suggested by Reversibility of Heart Effects</i> ; <u>Botulinum and Tetanus Neurotoxins</u> (edited by Dasgupta, B.R.); 1993 Plenum Press; 333-335.
<i>EEB</i>	CD	McDermott, D.A., et al.; <i>Use of an Indwelling Catheter for Examining Cardiovascular Responses to Pericardial Administration of Bradykinin in Rat</i> ; <u>Cardiovascular Research</u> ; 1995; Vol. 30; 39-46.

EXAMINER Bridget C. Bunner

DATE CONSIDERED 6/22/2001

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



LIST OF ART CITED BY APPLICANT

ATTY. DOCKET: 17310	SERIAL NO.: 09/371,354
APPLICANT: <del>AOKI et al.</del> <i>Donovan</i>	TITLE: METHOD FOR TREATING CARDIAC MUSCLE DISORDERS
FILING DATE: AUGUST 10, 1999	GROUP: <del>3734</del> 1647

UNITED STATES PATENTS

*EXAMINER INITIAL	DOCUMENT NO.	DATE	NAME	CLASS	SUB-CLASS	FILING DATE (if applicable)
AA						
AB						

FOREIGN PATENT DOCUMENTS

	DOCUMENT NO.	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATI (yes/no)
BA						
BB						
BC						
BD						

OTHER ART

(Including Author, Title, Date, Pertinent Pages, etc.)

<i>BBB</i>	CA	GALARDI ET AL.: "The Local Injection of Botulinum Toxin Can Effect the Neural Control of Heart Rate Variability.", <i>Nerology</i> , vol. 44, 1994, pages A307-A308
<i>BBB</i>	CB	KIMURA ET AL.: "Negative Chronotropic Effect of Botulinum Toxin on Neonatal Rat Cardiac Myocytes." <i>Biochem. Biophys. Res. Comm.</i> , vol 244, 1998, pages 275-279.
	CC	LAMANNA ET AL.: "Cardiac Effects of Botulinum Toxin." <i>Archives Internationales De Pharmacodynamie Et De Therapie</i> , vol 293, 1988 pages 69-83.
	CD	SAUVIAT M-P.: "Effect of Neurotoxins on The Electrical and Mechanical Activity of Heart Muscle.", <i>Comptes Rendus Des Seances De La Societe De Biologie Et De Ses Filiales</i> , vol. 191, 1997, pages 451-471.
	CE	
	CF	
	CG	
	CH	
	CI	

EXAMINER *Bridget E. Bunner*

DATE CONSIDERED *6/22/2001*

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# **Notice of References Cited**

Application/Control No.

09/371,354

Applicant(s)/Patent Under

Reexamination

DONOVAN, STEPHEN

Examiner

Bridget E. Bunner

6/25/01

Art Unit

1647

Page 1 of 1

## **U.S. PATENT DOCUMENTS**

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
	A	US-			
	B	US-			
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

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LEGAL/PATENTS

## **FOREIGN PATENT DOCUMENTS**

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

## **NON-PATENT DOCUMENTS**

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	Johnson, Eric. Clostridial toxins as therapeutic agents: benefits of nature's most toxic proteins. Annu Rev Microbiol 53: 551-575, 1999.
	V	Schmitt et al. Bacterial toxins: friends or foes? Emerg Infect Dis 5(2): 224-234, 1999.
	W	
	X	

\*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)  
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

<b>Notice of References Cited</b>	Application/Control No. <b>10/114,740</b>	Applicant(s)/Patent Under Reexam <b>Brooks</b>	
	Examiner <b>Portner</b>	Art Unit <b>1645</b>	Page 1 of 1

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**U.S. PATENT DOCUMENTS**

* X	A	Document Number Country Code-Number-Kind Code	Date MM-YYYY <sup>1</sup>	Name	SEP 4 2002	Classification <sup>2</sup>
		6,063,768	5/2000	First		514 14
		5,437,291	8/1995	Pasricha et al		128 898
		6,290,961	9/2001	Aoki et al		424 184.1
		6,319,505	11/2001	Aoki et al		424 236.1
		5,562,907	10/1996	Arnon		424 236.1
		6,429,189	8/2002	Borodic		514 2
		6,383,509	5/2002	Donovan et al		424 423
		5,851,786	12/1998	Johnson		435 29
		5,939,070	8/1999	Johnson et al		424 194.1
		6,238,872	5/2001	Mosseri		435 7.1
		6,299,893	10/2001	Schwartz et al		424 422
		6,102,904	8/2000	Vigil et al		604 500

**FOREIGN PATENT DOCUMENTS**

* N	O	P	Q	R	S	T	Document Number Country Code-Number-Kind Code	Date MM-YYYY <sup>1</sup>	Country	Name	Classification <sup>2</sup>

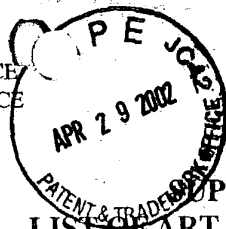
**NON-PATENT DOCUMENTS**

* U	V	W	X	Include, as applicable: Author, Title, Date, Publisher, Edition or Volume, Pertinent Pages
				Muniyappa, R et al, Am. J. Physiol. Heart Cir. Physiol., vol. 278, (6) pages H1762-H1768, June 2000.
				DePalma, GD et al, Endoscopy, Dec. 2001, Vol. 33(12), pages 1027-1030.
				Maria, G et al, Diseases of the colon & Rectum, 2000, Vol. 43(5), May, pages 721-723.
				Tan, EK et al, Movement disorders, Vol. 14(2), pages 345-349, 1999.

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<sup>1</sup> Dates in MM-YYYY format are publication dates.

<sup>2</sup> Classifications may be U.S. or foreign.



**SUPPLEMENTAL  
LIST OF ART CITED BY APPLICANT**

ATTY. DOCKET: 17310 (BOT)	SERIAL NO.: 09/371,354
APPLICANT: DONOVAN	TITLE: METHOD FOR TREATING CARDIAC MUSCLE DISORDERS BY ADMINISTRATION OF A BOTULINUM TOXIN
FILING DATE: AUGUST 10, 1999	GROUP: 1647

**U.S. PATENT DOCUMENTS**

*EXAMINER INITIAL		DOCUMENT NO.	DATE	NAME	CLASS	SUB-CLASS	FILING DATE (if applicable)
	AA						
	AB						
	AC						
	AD						
	AE						

**FOREIGN PATENT DOCUMENTS**

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	BC						

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<del>CA</del>	<del>AYER ET AL., "Amiodarone Instilled into the Canine Pericardial Sac Migrates Transmurally to Produce Electrophysiologic Effects and Suppress Atrial Fibrillation", J. Cardiovasc Electrophysiol, vol. 7, pp 713-721, August 1996</del>
<del>CB</del>	<del>GALARDI ET AL.: "The Local Injection of Botulinum Toxin Can Effect the Neural Control of Heart Rate Variability.", Neurology, vol. 44, 1994, pages A307-A308</del>
<del>CC</del>	<del>KIMURA ET AL.; "Negative Chronotropic Effect of Botulinum Toxin on Neonatal Rat Cardiac Myocytes." Biochem. Biophys. Res. Comm., vol 244, 1998, pages 275-279</del>
<del>CD</del>	<del>LAMANNA ET AL.: "Cardiac Effects of Botulinum Toxin." Arch. int. Pharmacodyn., vol 293, 1988 pages 69-83</del>

EXAMINER Bridget C. Bunner

DATE CONSIDERED 10/16/2002

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**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: Brooks	)	Examiner: Virginia Portner
	)	
Serial Number: 10/114,740	)	Art Unit: 1645
	)	
Filed: April 1, 2002	)	
	)	
For: METHODS FOR TREATING	)	
CARDIOVASCULAR DISEASES WITH	)	
BOTULINUM TOXIN	)	Irvine, California

**SUPPLEMENTARY INFORMATION DISCLOSURE STATEMENT**

Assistant Commissioner for Patents  
Washington, DC 20231

Dear Sir:

Applicant provides with regard to the above-identified patent application entitled METHODS FOR TREATING CARDIOVASCULAR DISEASES WITH BOTULINUM TOXIN, one copy of documents of which he is aware, which may be material to the examination of this application and in respect of which there may be a duty of disclosure under 37 C.F.R. §1.56. A listing of the documents submitted is set forth on the attached 1 page Information Disclosure Citation (Form PTO-1449).


While these documents may be material pursuant to 37 C.F.R. §1.56, their disclosure is not intended to constitute an admission that the documents are prior art in regard to this invention. The filing of this Statement should not be construed to mean that a search has been conducted or that no other material documents or information exists. Please do not hesitate to contact the undersigned should any questions arise regarding this Statement.

The Commissioner is hereby authorized to charge the fee for submission of an Information Disclosure Statement of \$180.00 to applicant's Deposit Account No. 01-0885. The Commissioner is further authorized to charge any other fees

associated with this communication, or credit any overpayment, to Deposit Account No. 01-0885.

Respectfully submitted,

Date: December 12, 2002

  
Stephen Donovan  
Registration Number 33,433

Please direct all inquiries and correspondence to:  
Stephen Donovan, Esq.  
Allergan, Inc.  
2525 Dupont Drive, T2-7H  
Irvine, California 92623-9534  
Tel: (714) 246-4026  
Fax: (714) 246-4249

**CERTIFICATE OF EXPRESS MAIL UNDER 37 C.F.R. §1.10**

I hereby certify that this Supplemental Information Disclosure Statement and the documents referred to as enclosed therein are being deposited with the United States Postal Service on **December 12, 2002** in an envelope as "Express Mail Post Office To Addressee" mailing label number EL897833205US with sufficient postage for Express Mail addressed to Assistant Commissioner for Patents, Washington, D.C., 20231.

Susan Bartholomew

Name of person mailing paper



Signature of person mailing paper

Date: December 12, 2002

**SUPPLEMENTAL  
LIST OF ART CITED BY APPLICANT**

ATTY. DOCKET: 17498 (BOT)	SERIAL NO.: 10/114,740
APPLICANT: BROOKS	TITLE: METHODS FOR TREATING CARDIOVASCULAR DISEASES WITH BOTULINUM TOXIN
FILING DATE: April 1, 2002	GROUP: 1645

**U.S. PATENT DOCUMENTS**

*EXAMINER INITIAL		DOCUMENT NO.	DATE	NAME	CLASS	SUB-CLASS	FILING DATE (if applicable)
	AA	5,766,605	6/16/98	Sanders et al			
	AB	6,464,986 B1	10/15/02	Aoki, et al.			
	AC						
	AD						
	AE						

**FOREIGN PATENT DOCUMENTS**

		DOCUMENT NO.	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION (yes/no)
	BB						

**OTHER ART**

(Including Author, Title, Date, Pertinent Pages, etc.)

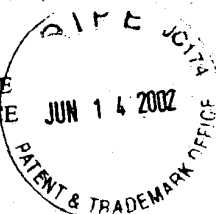
CA	Aktories, K., et al., <i>Clostridium botulinum C3 ADP-Ribosyltransferase</i> , Current Topics in Microbiology and Immunology, Vol. 175, 1992, 115-131
CB	Fauci, A.S., et al., <i>14<sup>th</sup> Edition Harrison's Principles of Internal Medicine</i> , McGraw-Hill, pp 904-907, 1998,
CC	Fiorentini, C. et al., <i>Bacterial toxins and the Rho GTP-binding protein: what microbes teach us about cell regulation</i> , Cell Death and Differentiation (1998) 5, pp. 720-728
CD	Nishiki, T., et al., <i>Morphological effects of clostridium botulinum C3 exoenzyme on cultured cells</i> , Jpn. J. Med. Sci. Biol. 43, 1990, 261-262.
CE	

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DATE CONSIDERED \_\_\_\_\_

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Sheet 1 of 2

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LIST OF ART CITED BY APPLICANT

ATTY. DOCKET: 17498 (BOT)	SERIAL NO.: 10/114,740
APPLICANT: GREG F. BROOKS	TITLE: METHODS FOR TREATING CARDIOVASCULAR DISEASES WITH BOTULINUM TOXIN
FILING DATE: APRIL 1, 2002	GROUP: 1614 <u>1645</u>

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NO.	DATE	NAME	CLASS	SUB-CLASS	FILING DATE (if applicable)
VJB	AA	5,092,841	3/3/92	Spears			
	AB	5,385,935	1/31/95	Tamai, et al.			
	AC	5,437,291	8/1/95	Pasricha, et al.			
	AD	5,989,280	11/23/99	Euteneuer, et al.			
	AE	6,063,768	5/16/00	First			
	AF	6,183,506 B1	2/6/01	Penn, et al.			
	AG	6,190,404 B1	2/20/01	Palmaz, et al.			
	AH	6,196,230 B1	3/6/01	Hall, et al.			
	AI	6,217,608 B1	4/17/01	Penn, et al.			
	AJ	6,239,118 B1	5/29/01	Schatz, et al.			
	AK	6,241,758 B1	6/5/01	Cox			
	AL	6,261,318 B1	7/17/01	Lee, et al.			
	AM	6,264,671 B1	7/24/01	Stack, et al.			
	AN	6,270,521 B1	8/7/01	Fischell, et al.			
	AO	6,293,959 B1	9/25/01	Miller, et al.			
	AP	6,306,162 B1	10/23/01	Patel			
	AQ	6,306,423 B1	10/23/01	Donovan, et al.			
	AR	6,312,708 B1	11/6/01	Donovan			
	AS	6,344,055 B1	2/5/02	Shukov			
	AT	09/678,189	--	Brooks, et al.			
AU	09/620,840	--	Steward, et al.			7/21/00	
AV	09/489,667	--	Donovan			1/19/00	
AW	09/922,093	--	Donovan			8/3/01	
AX	09/625,098	--	Donovan			7/25/00	
AY	09/910,346	--	Steward			7/20/01	

*not considered but not to be taken off*

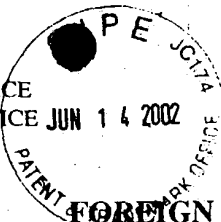
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*8/20/02*

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JUN 19 2002

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FOREIGN PATENT DOCUMENTS

		DOCUMENT NO.	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION (yes/no)
BP	BA	WO 01/10458A1	15/02/01	PCT			
	BB	WO 01/21213A2	29/03/01	PCT			

OTHER ART

(Including Author, Title, Date, Pertinent Pages, etc.)

BP	CA	Claus, D., et al., <b>Botulinum Toxin: influence on respiratory heart rate variation</b> , Mov Disord 1995 Sep; 10(5): 574-579
	CB	Girlanda, P., et al., <b>Botulinum toxin therapy: distant effects on neuromuscular transmission and autonomic nervous system</b> , J. Neurol Neurosurg Psychiatry 1992;55(9):844-5
	CC	Lamanna, C., et al., <b>Cardiac Effects of Botulinal Toxin</b> , Arch Int Pharmacodyn Ther 1988; 293: 69-83
	CD	Malnick, S., et al., <b>Fatal heart block following treatment with botulinum toxin for achalasia</b> , Am J Gastroenterol 2000;Nov; 95(11):3333-3334
	CE	Nebe, A., et al., <b>No effects on heart-rate variability and cardiovascular reflex tests after botulinum toxin treatment of cervical dystonia</b> , Mov Disord 1996 May; 11(3):337-339
	CF	Sathyamoorthy, V., et al., <b>Separation, purification, partial characterization and comparison of the heavy and light chains of botulinum neurotoxin types A, B and E</b> , The J. of Biol. Chem, Vol. 260, No. 19, Sep 5, pp. 10461-10466, 1985
	CG	Shone, C., et al., <b>A 50-kDa fragment from the NH2-terminus of the heavy subunit of clostridium botulinum type A neurotoxin forms channels in lipid vesicles</b> , Eur. J. Biochem 167, 175-180, 1987
	CH	Author Unknown, Internet, <b>Drug-coated stents help eliminate angioplasty problems</b> , March 18, 2002, <a href="http://www.cnn.com/2002/health/03/18/heart.angioplasty.ap/index.html">www.cnn.com/2002/health/03/18/heart.angioplasty.ap/index.html</a> . 3 pgs.

EXAMINER

*[Signature]*

DATE CONSIDERED

8/19/02

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**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: GREG F. BROOKS	) Examiner:
Serial Number: 10/114,740	)
	) Art Unit: 1614
Filed: April 01, 2002	)
	) Confirmation No. 9239
For: METHODS FOR TREATING	)
CARDIOVASULAR DISEASES	)
WITH BOTULINUM TOXIN	)
	) Irvine, California

**INFORMATION DISCLOSURE STATEMENT**

Assistant Commissioner for Patents  
Washington, D.C. 20231

Dear Sir:

Applicant provides with regard to the above-identified patent application entitled METHODS FOR TREATING CARDIOVASULAR DISEASES WITH BOTULINUM TOXIN, one copy of documents of which he is aware, which may be material to the examination of this application, and in respect of which there may be a duty of disclosure under 37 C.F.R. §1.56. A listing of the documents submitted is set forth on the attached 2 page Information Disclosure Citation (Form PTO-1449).

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ELB 9783806US

**LIST OF ART CITED BY APPLICANT**

ATTY. DOCKET: 17498 (BOT)	SERIAL NO.: 10/114,740
APPLICANT: GREG F. BROOKS	TITLE: METHODS FOR TREATING CARDIOVASULAR CISEASES WITH BOTULINUM TOXIN
FILING DATE: APRIL 1, 2002	GROUP: 1614

**U.S. PATENT DOCUMENTS**

*EXAMINER INITIAL		DOCUMENT NO.	DATE	NAME	CLASS	SUB-CLASS	FILING DATE (if applicable)
	AA	5,092,841	3/3/92	Spears			
	AB	5,385,935	1/31/95	Tamai, et al.			
	AC	5,437,291	8/1/95	Pasricha, et al.			
	AD	5,989,280	11/23/99	Euteneuer, et al.			
	AE	6,063,768	5/16/00	First			
	AF	6,183,506 B1	2/6/01	Penn, et al.			
	AG	6,190,404 B1	2/20/01	Palmaz, et al.			
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	AL	6,261,318 B1	7/17/01	Lee, et al.			
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	AO	6,293,959 B1	9/25/01	Miller, et al.			
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	AQ	6,306,423 B1	10/23/01	Donovan, et al.			
	AR	6,312,708 B1	11/6/01	Donovan			
	AS	6,344,055 B1	2/5/02	Shukov			
	AT	09/678,189	--	Brooks, et al.			10/4/00
	AU	09/620,840	--	Steward, et al.			7/21/00
	AV	09/489,667	--	Donovan			1/19/00
	AW	09/922,093	--	Donovan			8/3/01
	AX	09/625,098	--	Donovan			7/25/00
	AY	09/910,346	--	Steward			7/20/01

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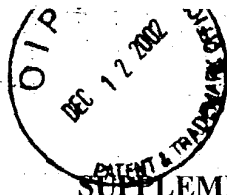
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	CA	Claus, D., et al., <b>Botulinum Toxin: influence on respiratory heart rate variation</b> , Mov Disord 1995 Sep; 10(5): 574-579
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	CC	Lamanna, C., et al., <b>Cardiac Effects of Botulinal Toxin</b> , Arch Int Pharmacodyn Ther 1988; 293: 69-83
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	CG	Shone, C., et al., <b>A 50-kDa fragment from the NH2-terminus of the heavy subunit of clostridium botulinum type A neurotoxin forms channels in lipid vesicles</b> , Eur. J. Biochem 167, 175-180, 1987
	CH	Author Unknown, Internet, <b>Drug-coated stents help eliminate angioplasty problems</b> , March 18, 2002, <a href="http://www.cnn.com/2002/health/03/18/heart.angioplasty.ap/index.html">www.cnn.com/2002/health/03/18/heart.angioplasty.ap/index.html</a> . 3 pgs.

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Sheet 1 of 1

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**SUPPLEMENTAL  
LIST OF ART CITED BY APPLICANT**

ATTY. DOCKET: 17498 (BOT)	SERIAL NO.: 10/114,740
APPLICANT: BROOKS	TITLE: METHODS FOR TREATING CARDIOVASCULAR DISEASES WITH BOTULINUM TOXIN
FILING DATE: April 1, 2002	GROUP: 1645

**U.S. PATENT DOCUMENTS**

*EXAMINER INITIAL		DOCUMENT NO.	DATE	NAME	CLASS	SUB-CLASS	FILING DATE (if available)
<i>VB</i>	AA	5,766,605	6/16/98	Sanders et al			
	AB	6,464,986 B1	10/15/02	Aoki, et al.			
	AC						
	AD						
	AE						

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TECH CENTER 1600/2900

**FOREIGN PATENT DOCUMENTS**

		DOCUMENT NO.	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION (yes/no)
	BB						

**OTHER ART**

(Including Author, Title, Date, Pertinent Pages, etc.)

<i>VB</i>	CA	Aktories, K., et al., <i>Clostridium botulinum</i> C3 ADP-Ribosyltransferase, Current Topics in Microbiology and Immunology, Vol. 175, 1992, 115-131					
	CB	Fauci, A.S., et al., 14 <sup>th</sup> Edition <i>Harrison's Principles of Internal Medicine</i> , McGraw-Hill, pp 904-907, 1998,					
	CC	Fiorentini, C. et al., <i>Bacterial toxins and the Rho GTP-binding protein: what microbes teach us about cell regulation</i> , Cell Death and Differentiation (1998) 5, pp. 720-728					
	CD	Nishiki, T., et al., <i>Morphological effects of clostridium botulinum C3 exoenzyme on cultured cells</i> , Jpn. J. Med. Sci. Biol. 43, 1990, 261-262.					
	CE						

EXAMINER

*VB*

DATE CONSIDERED

2/11/03

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

# **Notice of References Cited**

Application/Control No.  
**10/114,740**

Applicant(s)/Patent Under Review  
**Brooks**

Examiner  
**Portner**

Art Unit  
**1645**

Page 1 of 1

## **U.S. PATENT DOCUMENTS**

*	Document Number Country Code-Number-Kind Code	Date MM-YYYY <sup>1</sup>	Name	Classification <sup>2</sup>
A				
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M				

## **FOREIGN PATENT DOCUMENTS**

*	Document Number Country Code-Number-Kind Code	Date MM-YYYY <sup>1</sup>	Country	Name	Classification <sup>2</sup>
X	N 01/10458	2/2001	WO	Donovan	A61K 38/16
	O 01/82947	11/2001	WO	Unger	A61K 38/00
P					
Q					
R					
S					
T					

## **NON-PATENT DOCUMENTS**

*	Include, as applicable: Author, Title, Date, Publisher, Edition or Volume, Pertinent Pages
U	
V	
W	
X	

\* A copy of this reference is not being furnished with this Office action. See MPEP § 707.05(a).

<sup>1</sup> Dates in MM-YYYY format are publication dates.

<sup>2</sup> Classifications may be U.S. or foreign.

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: DONOVAN	)	Examiner: B. Bunner
	)	
Serial Number: 09/371,354	)	Art Unit: 1647
	)	
Filed: August 10, 1999	)	
	)	
For: METHOD FOR TREATING	)	
CARDIAC MUSCLE DISORDERS	)	
BY ADMINISTRATION OF A	)	
BOTULINUM TOXIN	)	
	)	Irvine, California

**RESUBMITTED SUPPLEMENTARY  
INFORMATION DISCLOSURE STATEMENT**

Assistant Commissioner for Patents  
Washington, DC 20231

Dear Sir:

Applicant provides with regard to the above-identified patent application entitled METHOD FOR TREATING CARDIAC MUSCLE DISORDERS BY ADMINISTRATION OF A BOTULINUM TOXIN, one copy of documents of which he is aware, which may be material to the examination of this application, and in respect of which there may be a duty of disclosure under 37 C.F.R. §1.56. A listing of the documents submitted is set forth on the attached 1 page Information Disclosure Citation (Form PTO-1449).

While these documents may be material pursuant to 37 C.F.R. §1.56, their disclosure is not intended to constitute an admission that the documents are prior art in regard to this invention. The filing of this Statement should not be construed to mean that a search has been conducted or that no other material

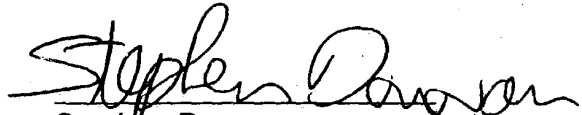


documents or information exists. Please do not hesitate to contact the undersigned should any questions arise regarding this Statement.

The Commissioner is hereby authorized to charge any fees required or necessary for the filing, processing or entering of this paper or any of the enclosed papers, and to refund any overpayment, to deposit account 01-0885.

Respectfully submitted,

Date: April 29, 2002

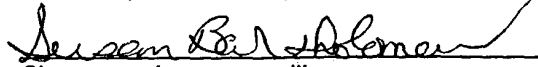
  
Stephen Donovan  
Registration Number 33,433

Please direct all inquiries and correspondence to:  
Stephen Donovan, Esq.  
Allergan, Inc.  
2525 Dupont Drive, T2-7H  
Irvine, California 92623-9534  
Tel: (714) 246-4026  
Fax: (714) 246-4249

**CERTIFICATE OF EXPRESS MAIL UNDER 37 C.F.R. § 1.10**

I hereby certify that this Supplementary Information Disclosure Statement and the documents referred to as enclosed herein are being deposited with the United States Postal Service on this date April 29, 2002, in an envelope as "Express Mail Post Office to Addressee" Mailing Label number EL897833735US addressed to BOX RCE, Commissioner for Patents, Washington DC 20231.

Susan Bartholomew  
Name of person mailing paper

  
Signature of person mailing paper

Date: April 29, 2002

**SUPPLEMENTAL  
LIST OF ART CITED BY APPLICANT**

ATTY. DOCKET: 17310 (BOT)	SERIAL NO.: 09/371,354
APPLICANT: DONOVAN	TITLE: METHOD FOR TREATING CARDIAC MUSCLE DISORDERS BY ADMINISTRATION OF A BOTULINUM TOXIN
FILING DATE: AUGUST 10, 1999	GROUP: 1647

**U.S. PATENT DOCUMENTS**

*EXAMINER INITIAL		DOCUMENT NO.	DATE	NAME	CLASS	SUB-CLASS	FILING DATE (if applicable)
	AA						
	AB						
	AC						
	AD						
	AE						

**FOREIGN PATENT DOCUMENTS**

		DOCUMENT NO.	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION (yes/no)
	BA						
	BB						
	BC						

**OTHER ART**

(Including Author, Title, Date, Pertinent Pages, etc.)

	CA	AYER ET AL., "Amiodarone Instilled into the Canine Pericardial Sac Migrates Transmurally to Produce Electrophysiologic Effects and Suppress Atrial Fibrillation", J. Cardiovasc Electrophysiol, vol. 7, pp 713-721, August 1996
	CB	GALARDI ET AL.: "The Local Injection of Botulinum Toxin Can Effect the Neural Control of Heart Rate Variability.", Neurology, vol. 44, 1994, pages A307-A308
	CC	KIMURA ET AL.; "Negative Chronotropic Effect of Botulinum Toxin on Neonatal Rat Cardiac Myocytes." Biochem. Biophys. Res. Comm., vol 244, 1998, pages 275-279
	CD	LAMANNA ET AL.: "Cardiac Effects of Botulinal Toxin." Arch. int. Pharmacodyn., vol 293, 1988 pages 69-83

EXAMINER \_\_\_\_\_

DATE CONSIDERED \_\_\_\_\_

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of DONOVAN )  
Serial Number: 09/371,354 ) Group Art Unit: 3734  
Filed: August 10, 1999 )  
For: METHOD FOR TREATING )  
CARDIAC MUSCLE DISORDERS ) Irvine, California

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents  
Washington, D.C. 20231

Dear Sir:

Applicant herewith submits a one page form PTO 1449 for consideration by the Examiner, consistent with the provisions of 37 CFR § 1.97 and 1.98. By submitting this Information Disclosure Statement, Applicant makes no admission that any item listed thereupon is material to the patentability of the invention claimed in the above-entitled patent application. Further, Applicant makes no assertion hereby that a search was conducted, or if conducted, that any search was thorough. Copies of the four references newly referenced in this Information Disclosure Statement are submitted herewith.

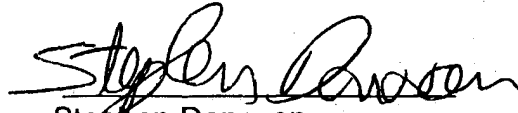
Also submitted herein is a copy of the International Search Report provided to the Applicant by the International Searching Authority in the counterpart PCT patent application of the above-identified patent application

Applicant respectfully requests that the Examiner indicate consideration of the cited references by returning a copy of the attached form PTO-1449 with the Examiner's initials or other appropriate marks. This Supplemental IDS is being submitted prior to the mailing of a first office action in this case and therefore no fee is believed due in connection with this communication.

Additionally, the references provided herein were cited in a communication from a foreign patent office in a counterpart patent application not more than three months prior to the filing of this Supplemental IDS.

If any fee is required please charge Deposit Account No. 01-0885 the appropriate amount.

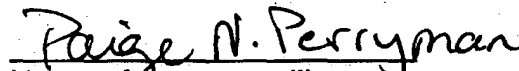
Date: December 27, 2000

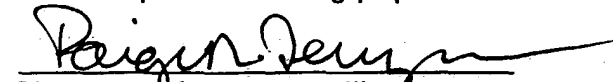
  
Stephen Donovan  
Registration Number 33,433

Allergan, Inc., Tower Two, Seventh Floor  
2525 Dupont Drive  
Irvine, California 92623-9534

**CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8**

I hereby certify that this Supplemental Information Disclosure Statement and the additional documents set forth above as being enclosed herein are being deposited with the United States Postal Service on the date shown below with sufficient postage as first class mail in an envelope addressed to Commissioner for Patents, Washington, DC 20231.

  
Name of person mailing paper

  
Signature of person mailing paper

Date: December 27, 2000

U.S. DEPARTMENT OF COMMERCE  
PATENT AND TRADEMARK OFFICE  
FORM PTO-1449

Sheet 1 of 1

## LIST OF ART CITED BY APPLICANT

ATTY. DOCKET: 17310	SERIAL NO.: 09/371,354
APPLICANT: AOKI et al.	TITLE: METHOD FOR TREATING CARDIAC MUSCLE DISORDERS
FILING DATE: AUGUST 10, 1999	GROUP: 3734

## UNITED STATES PATENTS

*EXAMINER INITIAL		DOCUMENT NO.	DATE	NAME	CLASS	SUB-CLASS	FILING DATE (if applicable)
	AA						
	AB						

## FOREIGN PATENT DOCUMENTS

		DOCUMENT NO.	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLAT (yes/no)
	BA						
	BB						
	BC						
	BD						

## OTHER ART

(Including Author, Title, Date, Pertinent Pages, etc.)

	CA	GALARDI ET AL.: "The Local Injection of Botulinum Toxin Can Effect the Neural Control of Heart Rate Variability.", <i>Nerology</i> , vol. 44, 1994, pages A307-A308
	CB	KIMURA ET AL.: "Negative Chronotropic Effect of Botulinum Toxin on Neonatal Rat Cardiac Myocytes." <i>Biochem. Biophys. Res. Comm.</i> , vol 244, 1998, pages 275-279.
	CC	LAMANNA ET AL.: "Cardiac Effects of Botulinal Toxin." <i>Archives Internationales De Pharmacodynamie Et De Therapie.</i> , vol 293, 1988 pages 69-83.
	CD	SAUVIAT M-P.: "Effect of Neurotoxins on The Electrical and Mechanical Activity of Heart Muscle.", <i>Comptes Rendus Des Seances De La Societe De Biologie Et De Ses Filiales.</i> , vol. 191, 1997, pages 451-471.
	CE	
	CF	
	CG	
	CH	
	CI	

EXAMINER \_\_\_\_\_ DATE CONSIDERED \_\_\_\_\_

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Sheet 1 of 1

# **Notice of References Cited**

Application/Control No.

09/371,354

Applicant(s)/Patent Under  
Reexamination  
DONOVAN, STEPHEN

Examiner

Bridget E. Bunner

800  
6/25/03

Art Unit

1647

Page 1 of 1

## **U.S. PATENT DOCUMENTS**

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
	A	US-			
	B	US-			
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

## **FOREIGN PATENT DOCUMENTS**

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

## **NON-PATENT DOCUMENTS**

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)			
*	U	Tsuboi et al. Botulinum neurotoxin A blocks cholinergic ganglionic neurotransmission in the dog heart. Jpn J Pharmacol 89(3): 249-254, 2002.			
	V	Tsuboi et al. Inotropic, chronotropic, and dromotropic effects mediated via parasympathetic ganglia in the dog heart. Am J Physiol Heart Circ Physiol 279: H1201-H1207, 2000.			
	W	Mangrum et al. The evaluation and management of bradycardia. N Eng J Med 342(10): 703-709, 2000.			
	X				

\*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)  
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

U.S. DEPARTMENT OF COMMERCE  
PATENT AND TRADEMARK OFFICE  
FORM PTO-1449

Sheet 1 of 2

## LIST OF ART CITED BY APPLICANT

ATTY. DOCKET: 17310	SERIAL NO.: 09/371,354
APPLICANT: DONOVAN, STEPHEN	TITLE:
FILING DATE: 08/10/1999	GROUP: 1647

## UNITED STATES PATENTS

## PATENT

*EXAMINER INITIAL		DOCUMENT NO.	DATE	NAME	CLASS	SUB-CLASS	FILING DATE (if applicable)
BBB	AA	5,766,605	6/16/98	Sanders et al.	424	239.1	6/1998
BBB	AB	5,865,794	2/2/99	Castro	604	53	2/1999

## OTHER ART

(Including Author, Title, Date, Pertinent Pages, etc.)

BBB	BA	Dickson, E., <i>Studies on the Manner in which the Toxin of Clostridium Botulinum Acts Upon the Body</i> , J. Exper Med 37: 711-31 (1923) d
	BB	Braunwald, E., <i>Heart Disease A Textbook of Cardiovascular Medicine</i> , fifth edition (1997), two volumes, W.B. Saunders Company
	BC	<del>Opie, L., <i>Drugs for the Heart</i>, fourth edition (1997), W.B. Saunders Company</del>
BBB	BD	Fauci, A., <i>Harrison's Principles of Internal Medicine</i> fourteenth edition (1997), McGraw Hill
	BE	Nattel, S., <i>Comparative Mechanisms of Action of Antiarrhythmic Drugs</i> , Am J. Cardiol, 72: 13F-17F (1993)
	BF	Wit, A., <i>Electrophysiological Basis for Antiarrhythmic Drug Action</i> , Clin. Physiol. Biochem. 3: 127-134 (1985)
	BG	Waxman, S., <i>Persistent Primary Coronary Dilation Induced by Transatrial Delivery of Nitroglycerin into the Pericardial Space: A Novel Approach for Local Cardiac Drug Delivery</i> , J Am Coll Cardiol 33: (7); 2073-2077 (1999)
	BH	Claus, D., <i>Botulinum Toxin: Influence on Respiratory Heart rate Variation</i> , Mov Disord 10(5): 574-9 (1995)
	BI	Kimura, K., <i>Negative Chronotropic Effect of Botulinum Toxin on Neonatal Rat Cardiac Myocytes</i> , Biochem Biophys Res Commun 6; 244 91): 275-9 (1998)
	BJ	Nebe, A., <i>No Effects on Heart-Rate Variability and Cardiovascular Reflex Tests After Botulinum Toxin Treatment of Cervical Dystonia</i> , Mov Disord; 11 (3): 337-9 (1996)
	BK	Glaradi, G., <i>The Local Injection of Botulinum Toxin can Affect the Neural Control of Heart Rate Variability</i> , Neural 44; (Sup 2): A307-A308 (1994)
	BL	Laham, R., <i>Therapeutic Myocardial Angiogenesis Using Percutaneous Intrapericardial Drug Delivery</i> , Clin Cardiol; 22 (supp 1): I6-19 (1999)
	BM	Laham, R., <i>Subxyphoid Access of the Normal pericardium: A Novel Drug Delivery Technique</i> , Cath & Cardiovasc Inter 47:109-111 (1999)
	BN	Sonobe, T., <i>Development of Intracoronary Local Adhesive delivery Technique</i> , Int. J Artic Organs 20(6); 319-326 (1997)
BBB	BO	Avitall, B., <i>Iontophoretic Transmyocardial Drug Delivery. A Novel Approach to Antiarrhythmic Drug Therapy</i> , Circulation 85: 1582-93 (1992)
	BP	Ayer GM, <i>Amiodarone Instilled into the Canine Pericardial Sac Migrates Transmurally to Produce Electrophysiologic Effects and Suppress Atrial Fibrillation</i> J Cardiovasc Electrophysiol 7: 713-21 (1996)

Bridget C. Dunne

6/22/2001

## PATENT DOCKET 17310

BEB	BQ	Labhasetwar V., <i>Epicardial Administration of Ibutilide from Polyurethane Matrices: Effects on Defibrillation Threshold and Electrophysiologic Parameters</i> J Cardiovasc Pharmacol 24: 826-40 (1994)
	BR	Lambert, C., <i>Local Drug Delivery</i> , Cath & Cardiovasc Diagn 41: 231 (1997)
	BS	Glazier, J., <i>Site-Specific Intracoronary Thrombolysis With Urokinase-Coated Hydrogel Balloons: Acute and Follow-Up Studies in 95 Patients</i> , Cath & Cardiovasc Diagn 41: 246-253 (1997)
	BT	Bartorelli, A., <i>Local Heparin Delivery Prior to Coronary Stent Implantation: Acute and Six Month Clinical And Angiographic Results</i> , Cath & Cardiovasc Diagn 42: 313-320 (1997)
	BU	Nebe, A., <i>Influence of Botulinum Toxin Type A on the Heart Rate Variability in Patients with Cervical Dystonia</i> , Mov Dis 10; 3: 389 (1995)
	BV	Claus, D., <i>Distant Effects of Botulinum Toxin on Autonomic Cardiac Reflexes</i> , Mov Dis 10; 3: 389 (1995)
	BW	Thomas, C., <i>Local Intracoronary Heparin Delivery With a Microporous Balloon Catheter</i> , Amer Heart J 132; 5: 969-972 (1996)
BEB	BX	Camemzind, E., <i>Site-Specific Intravascular Administration of drugs: History of a Method Applicable in Humans</i> , Cath & Cardiovasc Diagn 41: 342-347 (1997)

EXAMINER Budget C. Burner DATE CONSIDERED 6/22/2001

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Sheet 2 of 2